

REMARKS

In view of the present amendments and the comments which follow, and pursuant to 37 CFR §1.111, amendment and reconsideration of the Official Action of March 4, 2004 is respectfully requested by Applicants.

A Claims Listing dated 3/17/04 and specification pages marked to show changes have been submitted herewith.

The specification has been amended to insert serial numbers for pending patent applications and to delete the attorney docket numbers.

Claims 6-9, 19, 23, and 25-28 have been canceled without prejudice.

Claims 1-5, 10-18, 20-22, and 24 are currently pending and stand rejected

Miscellaneous problems

The Examiner has pointed out that Reference A22 on form PTO-1449 is missing a publication date. Applicants note that the printer will not cite this reference on the front of any patent which might issue based on this application; however, the publication date of the reference is unknown.

The Examiner has pointed out that the serial numbers of pending applications are missing from pages 8 and 13 of the specification. Applicants have supplied the missing serial numbers by way of the present amendment.

Rejection under 35 USC §112, first paragraph

Claims 1-28 have been rejected under 35 USC §112, first paragraph, because the specification, while being enabling for the preparation of a reagent comprised of CDI-activated particles to which an antibody is attached through the CDI moiety, does not reasonably provide enablement for a reagent in which the antibodies are attached to the

particles through any other point of attachment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims, as written, include the case wherein the antibody can be bound to the particle surface at any location and through any linkage (“linked to the surface through a covalent bond”). According to the language of claim 1, the use of the CDI-activated functionality on the particle is not required for the formation of the covalent bond between the particle and antibody. There is no enabling support for attachment of the antibody at any location other than through the CDI functionality.

As now amended, independent claims 1 and 13 now specifically recite that the binding agent is linked to the carbodiimide through a covalent bond. The arguments for rejection having thus been avoided or overcome, Applicants request the Examiner’s reconsideration of the rejection of claims 1-5, 10-18, 20-22, and 24 under 35 USC §112, first paragraph.

Rejection under 35 USC §112, second paragraph

Claims 1-28 have been rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. The Examiner has remarked that:

- (a) The claims are indefinite in not specifying where the antibodies are attached to the particles.
- (b) Claim 6 is a product claim which contains an improper method of use limitation. The limitation on the concentration of tertiary amine in the assay mixture is improper since the claim is drawn to the reagent which contains no sample (see also claim 13).

- (c) It is unclear what is meant by the claim 1 term “a binding agent” since the claim fails to indicate the nature/reactivity/specificity of the moiety which is to be bound to the particles.
- (d) In claim 17, there is no requirement that the antibody be the binding agent recited in claim 1 nor is there any requirement for where and how the antibody is placed on the reagent. For these reasons, the claim is indefinite and confusing. See also claims 18-20.
- (e) Claim 25 is indefinite and confusing in not specifying that the binding agent is specific for the analyte.

In response, Applicants have amended the claims as follows:

- (a) Independent claims 1 and 13 have been amended to specify that the binding agent is linked to the surface via the carbodiimide.
- (b) Claim 6 and claims 7-9 depending therefrom have been canceled without prejudice.
- (c) Claims 1 and 13 have been amended to specify that the binding agent is an antigen or antibody.
- (d) Claims 17, 18, and 20 have been amended to recite that the binding agent is specific for the analyte and forms a detectable complex with the analyte.
- (e) Claim 25 and claims 26-29 depending therefrom have been canceled without prejudice.

The arguments for rejection having thus been avoided or overcome, Applicants request the Examiner’s reconsideration of the rejection of claims 1-5, 10-18, 20-22, and 24 under 35 USC §112, second paragraph.

Applicants submit that their application is now in condition for allowance, and favorable reconsideration of their application in light of the above amendments and remarks is respectfully requested. Allowance of claims 1-5, 10-18, 20-22, and 24 at an early date is earnestly solicited.

* * * * *

The Examiner is hereby authorized to charge any fees associated with this Amendment to Deposit Account No. 02-2958. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

A handwritten signature in cursive script, reading "Marilyn L. Amick", written over a horizontal line.

Marilyn L. Amick
Reg. No. 30,444

Customer No. 23690
Roche Diagnostics Corp.
9115 Hague Road
Indianapolis, IN 46250
Phone: 317-521-7561
Fax: 317-521-2883